

Appl. No. 09/834,410
Amdt. dated March 3, 2006
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1615

PATENT

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A timed-release compression-coated solid composition for oral administration to a subject, said composition comprising:
 - a) a core tablet comprising a drug and a freely erodible filler, wherein said core tablet erodes approximately 40% to approximately 90% in the digestive tract of said subject, wherein said core tablet does not substantially contain a hydrogel-forming polymer;
 - b) an outer layer, wherein said outer layer is made from a hydrogel-forming polymer substance, and a hydrophilic base, wherein said hydrogel-forming polymer substance has a viscosity-average molecular weight of 2,000,000 or higher and/or a viscosity in an aqueous 1% solution (25° C) of 1,000 cp or higher, and said hydrophilic base having solubility such that the amount of water needed to dissolve 1g of said hydrophilic base is 5 mL or less; and
 - c) wherein the outer layer optionally contains another drug and the outer layer essentially does not contain the same drug as the core tablet drug.
2. (Canceled)
3. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein there is approximately 75 wt% or less of said drug, approximately 5 to approximately 80 wt% freely erodible filler, approximately 10 to approximately 95 wt% hydrogel-forming polymer substance, and approximately 5 to approximately 80 wt% hydrophilic base.
4. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more

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selected from the group consisting of malic acid, citric acid, tartaric acid, polyethylene glycol, sucrose, and lactulose.

5. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.

6. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler for a basic drug is 1 or 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.

7. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler for an acidic or neutral drug is 1 or 2 or more selected from the group consisting of polyethylene glycol, sucrose or lactulose.

8. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the hydrogel-forming polymer substance contains at least one type of polyethylene oxide.

9. (Canceled)

10. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the core tablet contains hydrogel-forming polymer substance.

11. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the hydrophilic base is 1 or 2 or more having solubility such that the amount of water needed to dissolve 1 g base is 5 mL or less.

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12. (Original) The timed-release compression-coated solid composition for oral administration according to claim 11, wherein the hydrophilic base is 1 or 2 or more selected from the group consisting of polyethylene glycol, sucrose, and lactulose.

13. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the hydrogel-forming polymer substance is at least 1 type of polyethylene oxide and further contains red ferric oxide and/or yellow ferric oxide.

14. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug is brought to be effectively released or absorbed in the lower digestive tract.

15. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug is brought to be effective for chronopharmacotherapy.

16. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug is metabolized by cytochrome P-450.

17. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug has the effect of inhibiting metabolism by cytochrome P-450.

18. (Original) The timed-release compression-coated solid composition for oral administration according to claim 16, wherein the drug is metabolized by CYP3A4.

19. (Original) The timed-release compression-coated solid composition for oral administration according to claim 17, wherein the drug has the effect of inhibiting metabolism by CYP3A4.

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20. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the drug is 4'-(2-methyl-1,4,5,6-tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide or its salt.

21. (Original) A method of timed release of a drug, whereby the composition in claim 1 is orally administered.

22. (Original) A method for alleviating undesirable drug interaction between a drug and other drugs used concomitantly that employ the same route for drug absorption, distribution, metabolism or excretion *in vivo* in humans, whereby the composition in claim 1 is orally administered.

23. (Original) A method of alleviating undesirable drug interaction with between a drug having the effect of inhibiting drug metabolism *in vivo* in humans and another drug according to claim 20 used concomitantly, whereby the composition in claim 1 is used.

24. (Original) In a hydrogel-forming compression-coated solid pharmaceutical preparation comprising: a core tablet containing drug and outer layer made from hydrogel-forming polymer substance and hydrophilic base, the improvement which comprises a timed-release compression-coated solid composition according to claim 1.

25. (Currently amended) In a hydrogel-forming compression-coated solid pharmaceutical preparation comprising:

a core tablet containing drug and outer layer made from hydrogel-forming polymer substance and hydrophilic base, the improvement which comprises a timed-release compression-coated solid composition for oral administration, said composition comprising:

(1) a drug and freely erodible filler are mixed with the core tablet, wherein said core tablet does not substantially contain a hydrogel-forming polymer;

(2) the percentage erosion of the core tablet is approximately 40 to approximately 90%;
and

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(3) the outer layer essentially does not contain the same drug as the above-mentioned drug.

26. (Original) The timed-release compression-coated solid composition for oral administration according to claim 25, wherein the drug is 4'-(2-methyl-1,4,5,6-tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzamilide or its salt.

27. (Currently amended) A timed-release compression-coated solid composition for oral administration, to a subject, said composition comprising:

a) a core tablet comprising a drug and a freely erodible filler, wherein said core tablet does not substantially contain a hydrogel-forming polymer, and wherein said core tablet erodes approximately 40% to approximately 90% in the digestive tract of said subject, wherein percentage erosion is determined by a method:

i) a compression-coated tablet is moistened for 3 hours in water at 37° C;
ii) the gelled part of the tablet is peeled off and the portion of the core tablet that has not eroded is removed;

iii) the core tablet is allowed to dry overnight in a dryer at 40° C and the weight is determined;

iv) the value obtained by subtracting dry weight from initial core tablet weight is multiplied by 100;

b) an outer layer, wherein said outer layer is made from a hydrogel-forming polymer substance, and a hydrophilic base, wherein said hydrogel-forming polymer substance has a viscosity-average molecular weight of 2,000,000 or higher and/or a viscosity in an aqueous 1% solution (25° C) of 1,000 cp or higher, and said hydrophilic base having solubility such that the amount of water needed to dissolve 1g of said hydrophilic base is 5mL or less; and

c) wherein the outer layer optionally contains another drug and the outer layer essentially does not contain the same drug as the core tablet drug.